

February 15, 2010

Via Federal Express
Hon. Blake A. Hawthorne, Clerk
Supreme Court of Texas
201 W. 14th Street, Room 104
Austin, Texas 78701

Re: No. 09-0073; *Merck & Co., Inc. v. Felicia Garza, et al.*; in the Supreme Court of Texas

Dear Mr. Hawthorne:

This post-submission letter brief on behalf of Respondents, Felicia Garza, et al., responds to the post-submission letter brief filed by Petitioner Merck & Co., Inc. on February 10, 2010 (Merck Ltr. Br.). I am enclosing an original and eleven copies, and requesting that you distribute copies to the justices.

Two themes emerge from Merck's post-submission brief. First, when interpreting this Court's decision in *Merrell Dow Pharmaceuticals, Inc. v. Havner*, Merck resorts to lower court opinions, federal district court opinions, extrapolations and conjecture, while disregarding the direct answers provided by the *Havner* opinion itself. Second, when reviewing the legal sufficiency of the evidence, Merck invites the Court to disregard the evidence supporting the jury verdict and look solely at the evidence that is contrary to the jury verdict, which could never be the correct standard of review. Rather, the Court "must view the evidence in the light favorable to the verdict, crediting favorable evidence if reasonable jurors could, and disregarding contrary evidence unless reasonable jurors could not." See *City of Keller v. Wilson*, 168 S.W.3d 802, 807 (Tex. 2005).

Interpreting *Havner*

Merck points out that some lower courts of appeals "have read *Havner* to establish minimum requirements for all epidemiological studies that must be satisfied in every case." Merck Ltr. Br. at ¶ 1. Other courts of appeals have expressly rejected the argument that *Havner* establishes a bright-line requirement for doubling of the risk, but

instead mandates a broader review of the evidence.¹ If anything, this inconsistency in the lower court opinions underscores the need for this Court to clarify that *Havner* means what it says.

To determine whether *Havner* articulates a bright-line test this Court need not look at the interpretations of *Havner* by the lower courts of appeals or federal district courts, because this question is addressed in the *Havner* opinion itself. Although the opinion states that “the requirement of more than a doubling of the risk strikes a balance between the needs of our legal system and the limits of science,” *Havner*, 953 S.W.2d at 718, the very next sentence states, “We do not hold, however, that a relative risk of more than 2.0 is a litmus test. . . .” *Id.* The opinion also states, “[T]here are a number of reasons why reliance on a relative risk of 2.0 as a bright-line boundary would not be in accordance with sound scientific methodology in some cases.” *Id.* at 719. The opinion ultimately concludes that courts should “determine from a totality of the evidence, considering all factors affecting the reliability of particular studies, whether there is legally sufficient evidence. . . .” *Id.* at 720. If some lower courts have misunderstood the flexibility embodied in the *Havner* opinion, that is no reason for this Court to now embrace a rigid and inflexible standard that is contrary to the practices of the scientific community that *Havner* attempted to embrace.

Merck addresses a question during oral argument from Justice Medina about whether it would be possible to establish causation with a relative risk of less than 2.0. Merck Ltr. Br. at ¶ 2. Although the *Havner* court observed that it did not need to decide that question in that case, *id.* at 719, the opinion does note, in explaining why a relative risk of 2.0 is not a litmus test, that “[E]ven if a particular study reports a low relative risk, there may in fact be a causal relationship.” *Id.* at 718.

¹ *Tex. Workers’ Comp. Ins. Fund v. Lopez*, 21 S.W.3d 358, 365 (Tex. App.—San Antonio 2000, pet. denied) (“[O]ur reading of *Havner* does not reveal a clear indication that a doubling of the risk is necessary for statistical significance.”); *Minn. Mining & Mfg. v. Atterbury*, 978 S.W.2d 183, 198 (Tex. App.—Texarkana 1998, pet. denied) (“[T]he court [in *Havner*] refused to set any strict rules regarding what type of evidence would be sufficient or not sufficient to support a finding of causation. There is no requirement in a toxic tort case that a party must have reliable epidemiological evidence of a relative risk of 2.0 or greater. Reliable epidemiological evidence with a relative risk lower than 2.0 should be considered because. . . it is relevant evidence.”). And as the court of appeals wrote in this case, “We do not construe *Havner* as narrowly as Merck, nor do we believe that *Havner* established such a bright-line test for causation. . . . [quoting three different passages from the *Havner* opinion] . . . We therefore follow *Havner*’s mandate to determine from a totality of the evidence whether there is legally sufficient evidence. . . .” *Merck & Co., Inc. v. Garza*, 277 S.W.3d 430, 435 (Tex. App.—San Antonio 2008, pet. granted).

Applying *Havner*

Merck raises Justice O’Neill’s question at oral argument, “Is there anything in *Havner* that says it has to be one study that hits all of the requirements?” Yet Merck’s answer is not responsive. Merck refers to a phrase in the *Havner* opinion stating that “an expert cannot dissect a study, picking and choosing data. . . .” Merck Ltr. Br. at ¶ 3 (quoting *Havner*, 973 S.W.2d at 720). The first part of the sentence that the quoted phrase comes from refers to Part VI.A. of the *Havner* opinion, which describes how the experts in that case found associations between Bendectin and birth defects “even though the authors of those studies did not find such an association.” *Id.* at 725. The rest of the quoted sentence represented by the ellipses explains that an expert cannot pick and choose data “or ‘reanalyze’ the data to derive a higher relative risk if this process does not comport with sound scientific methodology.” *Id.* at 720. But Merck has not introduced any evidence that the expert testimony presented by the Garzas either reached conclusions different from the authors of the studies or re-analyzed data to derive a higher relative risk. To the contrary, the Garzas introduced Merck’s own studies and let them speak for themselves. The snippet Merck offers from *Havner* is a red herring. More important, it is not responsive to Justice O’Neill’s question.

To respond to Justice O’Neill’s question, *Havner* does not declare that all of the requirements have to be met in one study. In fact, the opinion does not include a list of enumerated requirements; Merck has merely cobbled together a list of factors affecting reliability that are mentioned during the course of a lengthy opinion. Approaching the consideration of scientific reliability factors in a flexible manner is not unprecedented. In both *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and *E.I. DuPont de Nemours & Co., Inc. v. Robinson*, 923 S.W.2d 549 (Tex. 1995), the Courts referred to the famous six non-exclusive factors for the reliability of expert testimony as a “flexible inquiry.” *Robinson*, 923 S.W.2d at 557; *see also Daubert*, 509 U.S. at 557. And in the *Havner* opinion, when referring to the Bradford-Hill criteria of scientific reliability, this Court explained that, “epidemiologists do not consider it necessary that all these criteria be met before drawing inferences about causation. . . .” *Id.* at 719.

A flexible approach to applying reliability factors does not mean that litigants can cobble together a mythical study by taking a single study with a doubling of the risk, another with a confidence interval 95%, another using 25 milligrams dosage, and another producing adverse results in less than four weeks. But it does mean that a reviewing court should proceed as *Havner* directs: “Courts should allow a party, plaintiff or defendant, to present the best available evidence, assuming it passes muster under

Robinson, and only then should a court determine from a totality of the evidence, considering all factors affecting the reliability of particular studies, whether there is legally sufficient evidence to support a judgment.” *Id.* at 720. This is quite different from Merck’s suggested methodology, which is to judge each study by a rigid standard, and if every factor is not present in every study, then each is discarded and the sum total of proof is zero. But the process mandated by *Havner* is consistent with what happened in this case, where numerous studies were introduced, many of them highly reliable clinical trials, most of them conducted by Merck. If numerous studies show a doubling of the risk (as they did), and numerous studies reveal a confidence interval of 95% (which they did), and almost all of the studies were at a dosage of 25 milligrams or less (which they were), and numerous studies showed adverse results in less than 4 weeks (which they did), then it cannot be said that there is no evidence to support the jury verdict of general causation.

Merck attacks the VICTOR study because the final study was not published at the time of trial, and the document that was admitted consisted of “preliminary findings” that were still being “double checked.” Merck Ltr. Br. at ¶ 4. Yet in that document – which was admitted without objection, RR 6:112 – the sentence containing the phrases quoted by Merck also includes a statement by a Merck scientist that “I don’t expect the overall picture to change.” PX 111. If the final results did change, Merck could have offered evidence of that change, or ask the appellate courts to take judicial notice, but Merck did not do that. Merck also notes that an objection was sustained to Dr. Simonini testifying that the incidence of confirmed thrombotic events between Vioxx and placebo groups diverged “almost immediately.” Merck Ltr. Br. at ¶ 4 (citing RR 11:68-69). Yet that objection is irrelevant because Merck’s corporate representative already had confirmed that the lines on the chart began to diverge immediately. *See* RR 6:112-13. Finally, the almost immediate divergence of these lines is apparent in PX 111, which the Court can examine for itself. *See* Bench Exhibits of Respondents at tab B.

Merck attacks the Shapiro meta-analysis because it is “not a study at all.” Merck Ltr. Br. at ¶ 5. A meta-analysis analyzes and combines multiple studies. This one was undertaken by a Merck, which asked its employee, Deborah Shapiro, to analyze all existing studies on Vioxx. The meta-analysis demonstrated a combined increased risk of adverse cardiovascular events of 2.02, with a 95% confidence interval. *See* PX 279 (last page). Merck now criticizes its own methodology. Moreover, Merck seeks to remove one study from the meta-analysis and re-calculate the numbers to produce a different result, which is prohibited by *Havner*. *See Havner*, 953 S.W.2d at 720 (“an expert cannot

dissect a study, picking and choosing data, or ‘reanalyze’ the data to derive a [different] relative risk. . . .”).

Legal Sufficiency

Merck discusses Justice O’Neill’s question about the small abnormality revealed in the tip of Mr. Garza’s heart before his death being in a different area of the heart from the fatal clots. Merck Ltr. Br. at ¶ 6. Merck attempts to answer this question discussing only part of the evidence at trial: the testimony of Merck’s cardiology expert, Merck’s pathology expert, and Dr. Evans, a treating physician who was sued in this case and was openly hostile to the Garza family at trial. Merck ignores other evidence: the testimony of a cardiology expert, Dr. Simonini, and another treating physician, Dr. Posada, that the thalium scan performed on Mr. Garza revealed a minor area of diminished blood flow in the very tip of the heart; that this area reflected damage from a prior heart attack; that the area was unchanged from a prior thalium scan several years earlier, indicating it was not getting any worse; and that the area where the fatal clots occurred was getting good blood flow without any occlusion at the time of the thalium scan. See RR 11:92-95; 98-101; 12:59; 19:24. The question is not whether Merck presented any evidence that supported its causation theory, which the jury rejected. The question in a no evidence review of a jury finding of causation is whether there was any evidence to support the judgment that a reasonable jury would credit. *City of Keller*, 168 S.W.3d at 827. Here, there was, and Merck cannot demonstrate otherwise.

Finally, Merck argues that “there is no evidence that there were any clots in connection with Mr. Garza’ heart attack.” Merck Ltr. Br. at ¶ 7. Merck does not deny that the impartial County Medical Examiner found that the cause of death was two “fresh occlusions,” or blood clots. See PX 318; RR 10:60; 12:59. Instead, Merck claims that the autopsy report is “no evidence” because Merck’s pathology expert used a different microscope, interpreted the autopsy slides differently, and this amounts to rendering the autopsy report and the opinion of the County Medical Examiner “incompetent.” Merck Ltr. Br. at ¶ 7 (citing *City of Keller v. Wilson*, 168 S.W.3d 802, 813 (Tex. 2005)). Yet when *Keller* speaks of expert opinion testimony being “incompetent,” it mentions testimony by an expert who is not qualified, who makes unfounded factual assumptions, or whose testimony lacks a scientific basis. *Keller*, 168 S.W.3d at 812-13. Merck has not even preserved on appeal any argument that the Medical Examiner was not qualified, that he made unfounded factual assumptions, or that the opinion in the autopsy report lacks a scientific basis. A mere difference in professional judgment in the interpretation of autopsy slides between two qualified medical professionals does not mean that one

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opinion – especially the opinion believed by the jury – is incompetent and must be disregarded. Again, Merck cannot show that a reasonable jury could not credit the Garza's evidence. *See id.* at 827.

Merck's interpretation of *Havner* cannot be squared with the language of the opinion itself. Merck's arguments regarding legal sufficiency of the evidence cannot be squared with the record and the standard of review. This case should be affirmed, and the cause remanded for a new trial in accordance with the court of appeals opinion.

Sincerely,

/s/
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Felicia Garza, et al.

KD/gh
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